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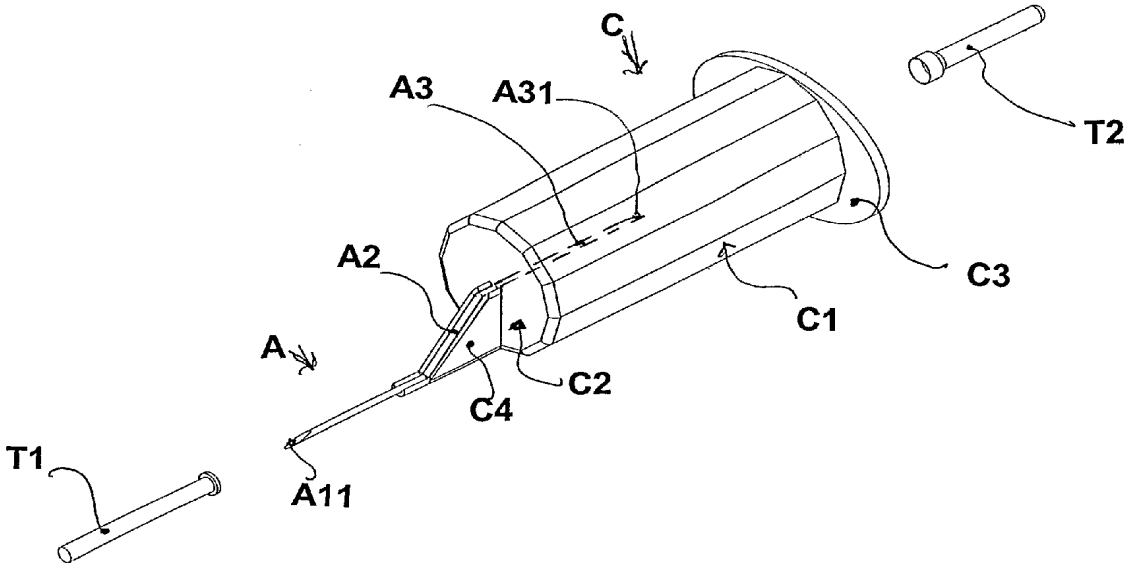
(54) Title: PROCESS FOR THE PRODUCTION OF INTERCHANGEABLE VACUUM TEST TUBE HOLDERS FOR TAKING BLOOD SAMPLES AND PRODUCT OBTAINED THEREFROM



(57) Abstract: The invention concerns a process for the production of cylindrical holders for vacuum test tubes and the holders obtained therefrom. The process includes the insertion of the straight needle into the moulded holder and the subsequent bending of the needle, so that its outer end adheres to the edge of the casing, thus facilitating the insertion of the needle into the vein. The new disposable holder is particularly useful for said blood sampling, as it guarantees the alignment of the needle with respect to the vein.

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TITLE

PROCESS FOR THE PRODUCTION OF INTERCHANGEABLE VACUUM TEST TUBE HOLDERS FOR TAKING BLOOD SAMPLES AND PRODUCT OBTAINED THEREFROM

DESCRIPTION

This patent concerns devices for taking blood samples and in particular it concerns the holders provided with needle, for veins or arteries, in which the vacuum test tubes for taking blood samples are inserted and the process for their production.

Many medical diagnoses require the analysis of blood samples which are taken directly from the patient's vein.

When blood samples are taken, it is very important to prevent the transmission, both between patients and between patient and nurse, of any diseases, germs, viruses and similar.

The nurse must not insert the needle through the vein, penetrating it from side to side, because this produces a haematoma in the patient and also because it makes it impossible to take the blood sample.

The syringe, as a means of taking blood samples from the patient, has been replaced by a holder provided with needle, integral with it, and various vacuum test tubes that are inserted in said holder each time.

The holder consists of a plastic cylinder with the rear end open and the front end closed by a circular wall through which the needle passes.

Said cylinder, which is suited to contain the vacuum test tube, has the disadvantage of being very wide.

Part of the needle outside the holder is inserted in the vein from which the blood sample is to be taken, while the tip of the needle which is housed inside the holder pierces the seal cap of the vacuum test tube inserted in the holder, thus conveying the blood inside said vacuum test tube.

The holders with needle with two opposite tips currently known have the needle positioned centrally, or coaxially, with respect to the holder.

During the taking of blood samples, when the needle of the holder is inserted in the patient's vein, the needle penetrates the skin at a very wide angle, as the thickness of the holder makes it impossible to position the needle near the skin in a substantially tangential position. The nurse is therefore obliged to contrive various solutions, such as raising the patient's skin or pressing the holder hard against the patient's skin. All this does not prevent possible perforation of the vein, however.

Furthermore, said contrivances cause discomfort and in some cases even pain to the patient.

Since the tip of the needle is slanted or lance-shaped, for better insertion in the skin and in the vein, each time the nurse must check the position of the tip of the needle, which must have its oblique side facing upwards for correct insertion into the skin and vein.

Some nurses use butterfly needles, i.e. small needles provided at the sides with two flat flexible grips and provided with a connection tube for the support or for the syringe. These butterfly needles simplify insertion into the vein and make the blood sampling less painful, but the nurse has to prepare the butterfly needle, connect it to the support or syringe, insert the butterfly needle into the vein and keep it in position with her/his hand or a plaster throughout the sampling operation.

Furthermore, butterfly needles are expensive to purchase and dispose of.

Holders exist that are provided with non-central needle, i.e. a needle positioned near the side wall of the holder and parallel to it.

These holders are described in the patent US 5938622.

Although these holders theoretically permit better insertion of the needle into the vein, they are expensive and difficult to produce. These vacuum

test tubes, in addition to being expensive to purchase, must be inserted correctly in the holder, i.e. with the eccentric pierceable area perfectly aligned with the needle inside the holder.

Holders with the needle bent at two points, i.e. roughly S-shaped with the two end parts parallel and the intermediate part slanting, are also known.

The part of the needle inside the holder is generally central to or coaxial with the holder, whereas the outer part of the needle is eccentric and out of line.

Said holders with needle bent at two points are described in the patent US 3520292.

The production of said holders with needle bent at two points requires the pre-bending of the needle, the creation around its slanting part of the circular wall which constitutes the bottom of the holder and, lastly, the creation of the cylindrical wall of the holder.

All said work phases involve lengthy production times, the need to position and align the various parts, the possibility of inaccuracy and imperfect joining of the various parts.

Consequently, the production of said holders with bent needle is very costly.

Said holders with bent needle are not convenient for use, also due to the fact that in practice their production process does not allow the outer part of the needle to be positioned in correspondence with the outer edge of the casing. Said distance of the needle from the edge of the casing, albeit shorter than the distance existing in the holders with central needle, limits the insertion of the needle into the vein and all the sampling operations.

In order to eliminate the above-mentioned disadvantages, a new process has been designed for the production of holders with needle bent at two points which can be used with interchangeable vacuum test tubes for taking blood samples.

The aim of the new process is to produce a holder with needle bent at two points in only a few simple stages.

A further aim of the new process is to produce a holder with needle bent at two points having the outer part of the needle practically aligned with the outer edge of the casing, that is, with a much narrower or nil penetration angle.

A further aim of the new process is to produce a holder with needle bent at two points without the possibility of inaccuracy, imperfections, non-alignments or incorrect orientation.

The aim of the new holder with needle bent at two points is to facilitate the insertion of the holder needle into the vein without causing the patient discomfort or pain.

A further aim of the new holder is to facilitate the insertion of the holder needle into the vein with no need for the nurse to check the position of the tip of the needle.

A further aim of the new holder is to facilitate the insertion of the holder needle into the vein with no need for the nurse to raise the patient's skin.

A further aim of the new holder is to facilitate the insertion of the holder needle into the vein, avoiding the risk of perforating the vein from side to side.

A further aim of the new holder is to permit the use of common vacuum test tubes provided with seal cap suitable for central perforation.

These and other direct and complementary aims are achieved through the implementation of the new process for the production of holders with needle bent at two points which can be used with interchangeable vacuum test tubes for taking blood samples and through the product obtained therefrom.

The new holder, which is preferably of the disposable type, comprises a generically cylindrical casing closed at one end, designed to receive

vacuum test tubes with seal cap for central perforation, and a shaped needle, preferably consisting of two parallel straight sections not lying on the same axis, joined by a further slanting or generically S-shaped section, said needle being joined to the casing so that its portion inside the casing is coaxial with said casing and so that its portion outside the casing and facing the same is shaped and, in its end part, parallel and eccentric to the axis of the casing, while an outer support wall or front connection wall acts as a thrust bearing for the needle.

The casing features a wall designed to house and join the angled, bent or shaped section of the needle to the casing.

The holder also has the advantage of being disposable, thus avoiding all possible risks for the users.

The process for the production of the new holder with needle bent at two points includes the complete production of the casing with connection wall, the insertion of the needle still straight and with the angled ends correctly oriented into the end circular wall of the casing, the fixing of said needle to said circular wall, the double bending of the needle until it adheres to the slanting connection wall and is aligned with the outer edge of the casing and the final fixing of the needle to the end of the slanting connection wall.

Said connection wall or outer support wall can be used as a grip for the new holder.

The characteristics of the new process for the production of the new holder with needle bent at two points and of the product obtained therefrom will be better illustrated by the following description, with reference to the drawings attached as a non-restrictive example.

Figure 1 shows an axonometric view of the new holder, comprising a casing (C) and a shaped needle (A). Figure 2 shows a cross section of said holder.

The shaped needle (A) consists of three consecutive sections (A1, A2,

A3), of which the two extreme sections (A1, A3) are parallel and not lying on the same axis. The intermediate section (A2) connects said two extreme sections (A1, A3) and is slanting with respect to each of them.

Both said extreme sections (A1, A3) have angled or slanting tip (A11, A31), in order to permit the penetration into the skin and vein and the perforation of and penetration into the seal cap of a vacuum test tube, respectively.

The casing (C) consists of a cylinder (C1) closed on the front side (C2) and provided with outer tabs (C3) at the other end.

On the front closing wall (C2) of the casing (C) the shaped needle (A) is applied, so that an end section (A3) of said needle (A) is inside the casing (C), coaxial with the cylindrical part (C1) of the casing (C).

The other end (A1) of the shaped needle (A) is outside the casing (C) and substantially aligned with the lower outer cylindrical surface of the casing (C).

Due to the position of the shaped needle (A) with respect to the casing (C), its intermediate section (A2) is outside the casing (C) and facing the front closing wall (C2) of the casing (C).

The tip (A1) of the needle (A) that is outside the casing (C) has the angled, or slanting side (A11) facing upwards or facing the centre or the axis of the casing (C).

The casing (C) features a connection wall (C4) designed to house and connect the intermediate section (A2) of the needle (A) with the casing (C). The lower edge of said connection wall (C4) is parallel to the last outer section (A1) of the needle (A) and provides a sliding surface for the holder (C) during the introduction of the needle (A).

The contact surface between said connection wall (C4) and the needle (A), in particular the intermediate slanting section (A2) of the needle (A), is generically semicircular, preferably with a slight undercut, in order to

correctly house and retain the needle (A).

This connection or support wall (C4) can be used as a grip for the new holder.

Two caps (T1, T2) are provided, which can be applied to protect and cover the end sections (A1) and (A3) and the two tips (A11, A31) of the needle (A).

The casing (C), or part of it, can bear the colour of the needle gauge international code.

Figure 3 shows in section a possible variant of the invention, in which the needle (A) is bent in two parts (A1a, A3a), of which an end part (A3a) of the needle (A) is included inside the casing (C) and is coaxial with it, while the other end part (A1a) of the needle (A) is outside the casing (C) and slanting with respect to said casing (C).

The process for the production of said new holder with needle bent at two points comprises only a few simple stages.

Initially the whole casing (C) is produced, preferably by moulding of thermoplastic material, with the outer tabs (C3) and with the slanting connection wall (C4). The hole housing the needle (A) is provided on the front wall (C2).

The needle (A), linear and not bent, is inserted in said hole of said front wall (C2) of the casing, in such a way as to correctly position its end section (A3) inside the casing.

In this insertion phase, the needle (A) is already positioned with the slanting tip (A11) correctly arranged, in particular facing upwards with respect to the connection wall (C4).

At this point the needle (A) is fixed to the front wall (C2) of the casing (C), for example by means of glue.

Subsequently the needle (A) is bent twice: the first operation bends the

needle (A) so that it adheres to the connection wall (C4), and in particular positioning it in the semicircular housing of said wall (C4); the second bending operation, at the end of the connection wall (C4), aligns the end section (A1) of the needle (A) with the outer surface of the casing (C) and with the sliding surface of the connection wall (C4).

Lastly, the two sections (A1, A2) of the needle (A) outside the casing (C) are fixed to the connection wall (C4), preferably by means of glue, in correspondence with the end of the connection wall (C4) opposite the casing (C).

The method described above for the production of the new holder with needle bent at two points requires the simple moulding of the casing (C) and the preparation of the needle (A) straight with angled tip (A11), the insertion of the needle (A) into the casing (C) and, lastly, the bending and joining of the needle (A) to the casing (C) and to the connection wall (C4).

The new holder constituted and produced as described above offers considerable advantages.

After removing the cap (T1) from the needle (A), the nurse grips the new holder by its cylindrical body (C1) or the wall or connection wall (C4), leaving the outer section (A1) of the needle (A) facing downwards. Consequently, the new holder in the nurse's hand is already in the correct position for use, with the tip (A11) of the needle (A) already correctly facing upwards with respect to the patient's skin and vein.

The eccentric position of the needle (A1) with respect to the casing (C), and in particular its position aligned with the outer surface of the casing (C), allows the nurse to insert the needle (A) into the skin and vein with minimum penetration angle.

The new holder, with its greatly reduced or nil penetration angle, significantly reduces the discomfort or pain caused to the patient and

avoids possible vein perforation errors.

The new holder, with its greatly reduced penetration angle, facilitates the insertion of the needle (A) into the vein.

The new holder with the eccentric needle (A) allows the nurse to correctly insert the needle (A) into the vein with no need to take any particular precautions, such as raising the patient's skin or varying the penetration angle during penetration.

The reduced penetration angle of the new holder considerably reduces the risk of perforating the vein from side to side.

The new holder, having the needle section (A3) inside the casing (C) positioned coaxially with the casing itself, permits the use of the common and widespread vacuum test tubes with seal cap for central perforation.

Therefore, with reference to the preceding description and the attached drawings, the following claims are put forth.

CLAIMS

1. Process for the production of holders for vacuum test tubes, comprising a cylindrical casing (C), designed to house said vacuum test tube for blood sampling, provided with a needle (A) partially housed in said casing (C), with the inner section (A3) of the needle (A) generically coaxial with the casing (C), characterised in that it comprises:

- the production of the whole casing (C), preferably by moulding of thermoplastic material, with the hole suitable for housing the needle (A) on the front wall (C2) and with support wall or lower connection wall (C4) generically triangular in shape and having one side adhering to the front wall (C2) between said hole and the outer cylindrical surface of the casing (C) and one lower side aligned with said cylindrical wall of the casing (C);
- the insertion of the needle (A) straight, with the angle of the tip (A11) facing upwards, i.e. with oblique cut, into said hole in the end wall (C2) of the casing (C) and the fixing of said needle (A) in correspondence with the front wall (C2), in such a way as to house the inner part (A3) of the needle (A) inside the casing (C);
- a first bending of the needle (A) to slant it with respect to the axis of the casing (C) and make it adhere to the slanting side of the connection wall (C4);
- a further bending of the outer part (A1) of the needle (A) to align the end section (A1) of the needle (A) with the outer surface of the casing (C);
- the fixing of the needle (A) to the connection wall (C4), preferably on the end of said wall (C4) opposite the casing (C).

2. Holder to be used with interchangeable vacuum test tubes for taking blood samples, characterized in that it comprises a casing (C), generically

cylindrical with a closing wall (C2) at one end, provided with a needle (A) bent in at least three parts, of which the two end parts (A1, A3) are parallel, not lying on the same axis, and the intermediate part (A2), connecting said two parts (A1, A3), is external to said casing (C) and is slanting, and wherein said needle (A) is applied to the end wall (C2) of the casing (C), so that an end part (A3) of the needle (A) is inside the casing (C) and is coaxial with it, and wherein the other end part (A11) of the needle is outside the casing (C) and generically aligned with the outer surface of the casing (C), and wherein said casing (C) is provided on its end wall (C2) with a wall or wall (C4) designed to house the intermediate section (A2) of the needle (A) and to connect it with the casing (C) and provides a lower sliding surface for the holder (C) during the introduction of the needle (A).

3. Holder for interchangeable vacuum test tubes for taking blood samples, characterized in that it comprises a casing (C), generically cylindrical with a closing wall (C2) at one end, provided with a needle (A) bent in two parts (A1a, A3a), and wherein said needle (A) is applied to said end wall (C2) of the casing (C), so that a part (A3a) of the needle (A) is inside the casing (C) and is coaxial with it, and wherein the other part (A1a) of the needle (A) is outside the casing (C) and slanting with respect to the casing (C), and wherein said casing (C) is provided on its end wall (C2) with a connection wall (C4) designed to house the outer part (A1a) of the needle (A) and to connect it with the casing (C) and provides a lower sliding surface for the holder (C) during the introduction of the needle (A).

4. Holder for interchangeable vacuum test tubes for taking blood samples according to the previous claims, characterized in that the connection wall (C4) of the casing is provided with a semicircular seat suitable for housing and fixing the needle (A).

5. Holder for interchangeable vacuum test tubes for taking blood

samples according to the previous claims, characterized in that the outer tip (A1) of the needle (A) has its angled or slanting side (A11) facing upwards.

6. Holder for interchangeable vacuum test tubes for taking blood samples according to the previous claims, characterized in that it is provided with at least one cap (T1) that can be applied to protect and cover the tip (A11) of the needle (A) (bent once).

7. Holder for interchangeable vacuum test tubes for taking blood samples according to the previous claims, characterized in that the surface of the casing (C) bears a colour and/or wording indicating the international code of the needle gauge.

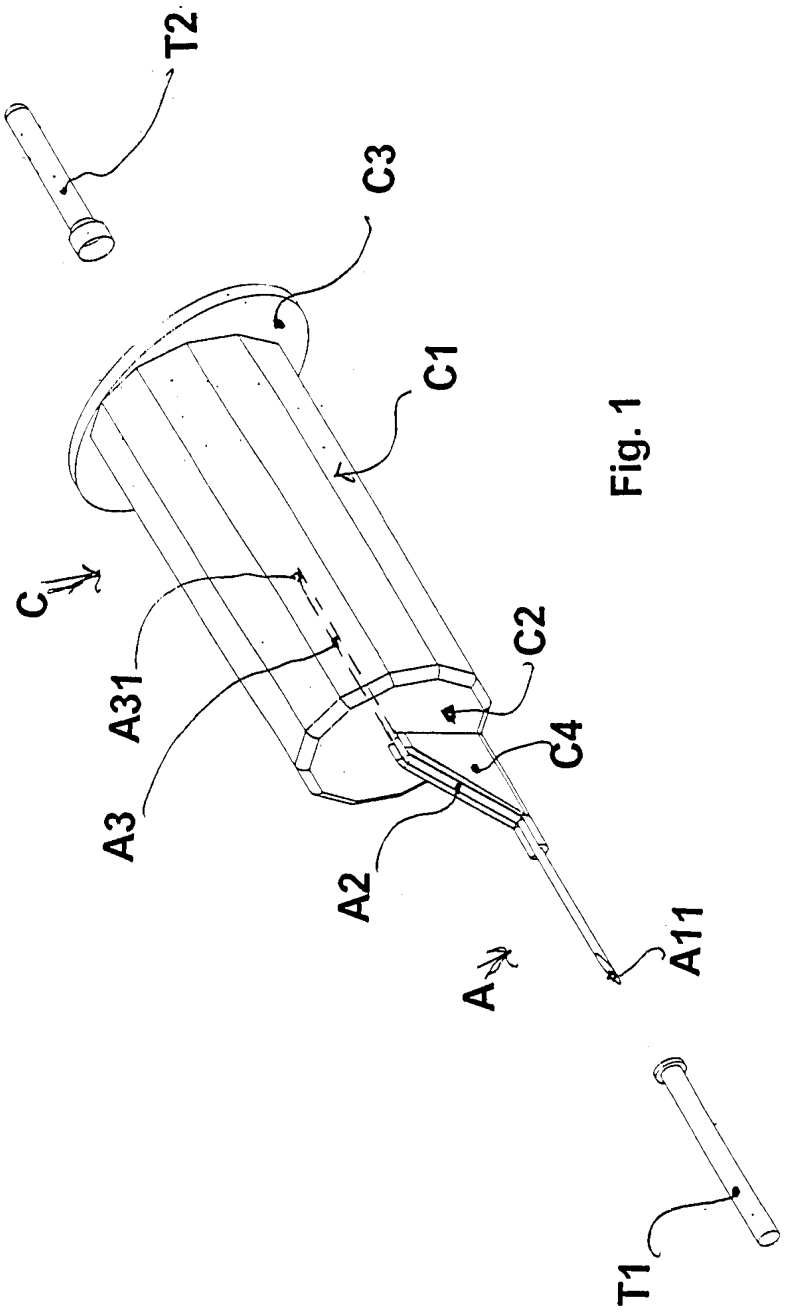

Fig. 1

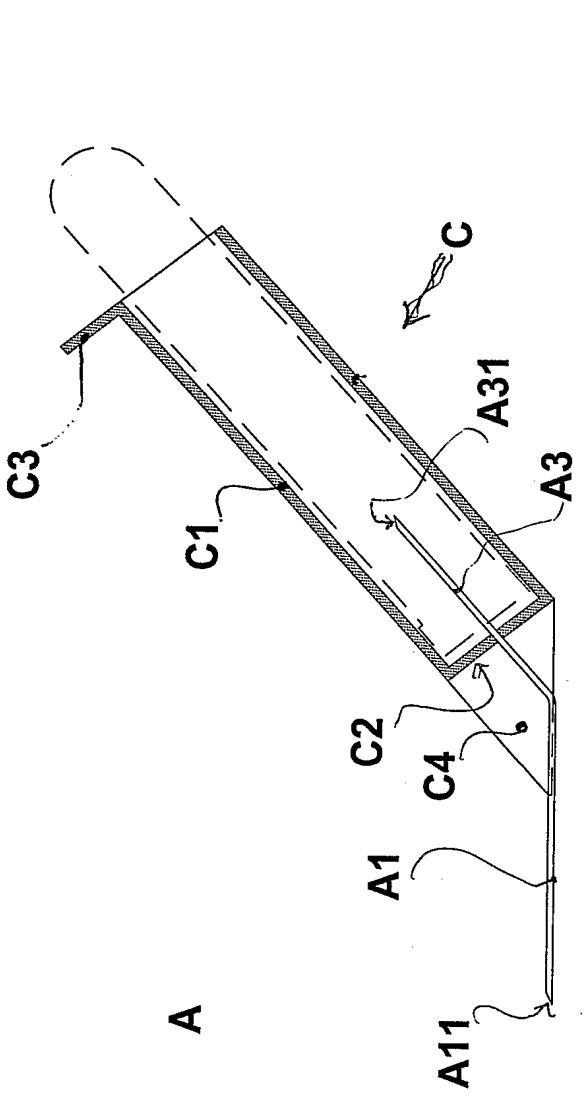

Fig. 3

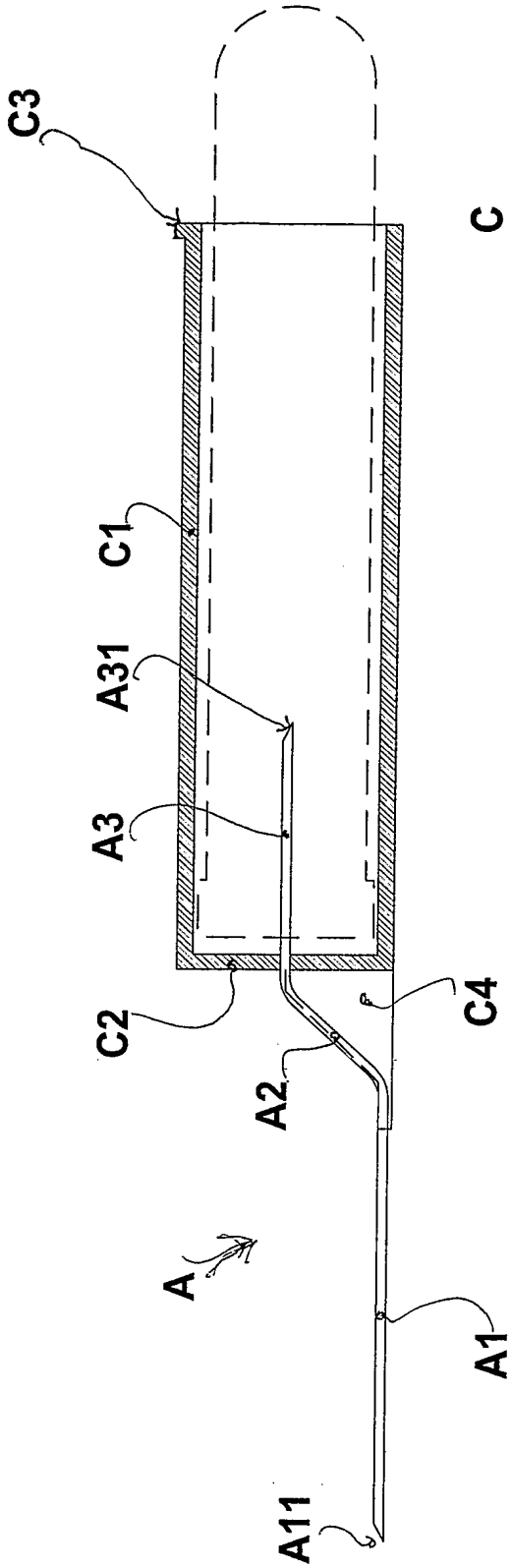

Fig. 2

CORRECTED VERSION

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 03/00713

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 188 119 A (SUNDERLAND RICHARD A) 23 February 1993 (1993-02-23)	2,4-7
A	column 9, line 67 - column 10, line 42; figures 1,9	1

X	US 3 326 206 A (BARR JR COURTLAND H ET AL) 20 June 1967 (1967-06-20)	2,4-7
A	column 3, lines 16-63; figures 1-5	1

X	EP 0 732 077 A (FROREICH ANDRE VON) 18 September 1996 (1996-09-18) column 6, line 20 - column 7, line 28; figures 4,5	3-7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 July 2004	23. 07. 2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ceccarelli, D

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IT 03/00713

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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